

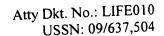
In the above-referenced Official Action it was stated that:

"The claim is drawn to a "gimbaled compression pad" in combination with a bladder. The Office has read the gimbaled compression pad in light of the page 4 lines 8+ of the (applicants) specification. The description in the (applicant's) specification is indistinguishable from the above cited art."

Applicants' application, wherein as described by the language of Claim 1, the present invention is directed toward a **gimbaled actuator**, wherein the gimbaled actuator is configured to apply uniform pressure to a bladder, the bladder being disposed on a test strip or similar device. It is the Applicants belief that the 35 U.S.C. § 102(b) rejection was premised on the improper belief that Claim 1 of the Applicants' application was directed toward **a test strip** including a bladder, wherein, in fact the claims are directed to the gimbaled actuator itself.

It is well established that in order to present a rejection under 35 U.S.C. §102(b) the reference must teach <u>every</u> element of the present invention. See <u>Rowe v. Dror</u>, 42 USPQ.2d 1550, wherein the court held: "Anticipation requires that prior art references disclose expressly or inherently <u>every</u> limitation contained in the claim."

The Applicants respectfully disagree with the 35 U.S.C. 102(b) rejection because the prior-art cited in the Official Action does not teach or suggest every element of the present invention. Specifically, none of the prior-art references cited teach the use of a gimbaled actuator to compress a reservoir disposed on a disposable test strip. Hurtig et al. discloses the use of a person's finger to compress the resiliently collapsible chamber. (See abstract) Kyoto (EP 0803288) also discloses a compressible chamber that is compressed by users fingers. (See page 24, lines 46-48). Lastly, Davis (WO 95/12117) discloses the use of a plunger to compress a diaphragm, though, the plunger does not include or suggest the use of a gimbaled actuator.



Therefore, the prior art cited in the above-referenced Office Action does not anticipate the present invention because the references fail to teach a gimbaled actuator, and this rejection of Claims 1-13 under 35 U.S.C. §102(b) should be withdrawn.

Rejection under 35 U.S.C. §103(a)

Claims 2-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hurtig et al., Davis, EP 0803288 (EP Hereafter) or WO 95/12117 (WO hereafter).

It was stated in the above-referenced Official Action that:

"See Hurtig et al., Davis, EP 0803288 and WO 95/12117, supra. The cited art is silent as to automation of the pad and the claimed dimensions of the pad.

"The court decided In re Venner (120 USPQ 192) that it is well known to automate a manual process. It would have been within the skill of the art to modify Hurtig et al., Davis, EP 0803288 and WO 95/12117 to provide automation means to depress the bulb to draw in a sample in view of Venner above."

Additionally, it was stated that:

"The court decided <u>In re Rose</u> (105 USPQ 237) that changes in the size are within the skill of the art. It would have been within the skill of the art to modify Hurtig et al., Davis, EP 0803288 and WO 95/12117 to have the compression area from about 0.19 to 0.21 square inches in view of Rose above.""

Applicant respectfully directs the Examiner's attention to the following, wherein the law is clear that to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 21 USPQ2d 1941 (Fed. Cir. 1992). Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 231 USPQ 375 (Fed. Cir. 1986). Finally, the prior art reference, or references when combined, must teach or suggest all the claim limitations. *In re Royka*, 180 USPQ 580 (CCPA 1974).

Referring specifically to Column 2, lines 42-56 of Hurtig et al., there is described that the collapsible chamber of Hurtig et al., is collapsed by squeezing the chamber by a



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users finger prior to placing the tube entry end into the fluid being collected. The operator controls the expansion of the chamber walls until he has collected the desired volume of sample. Thus, Hurtig et al. does not teach or suggest the use of a gimbaled actuator.

Directing the Examiner's attention to page 10 of Davis (WO 95/12117), second paragraph, there is described a plunger that is utilized for compressing the diaphragm of the device. The motion of the plunger of Davis is not described other than in general terms that the plunger is utilized to compress the diaphragm. As described in the Applicants' application and recited in the claims, the **gimbaled** actuator provides constant and even pressure across a compressible member. This constant pressure is unlike the plunger as described in Davis, which may apply uneven forces to the compressible member. These uneven forces are undesirable because errors may be introduced into the test due to the variations in the bladder volume through the compression and decompression cycle. Thus, Davis also fails to teach or suggest the use of a gimbaled actuator.

Directing the Examiner's attention to Column 24, lines 46-48 of EP 0803288, Kyoto Daiichi, there is described that the suction generating means are compressed utilizing a **persons finger** and not a mechanical device, and more specifically Kyoto **does not** describe the use of a gimbaled actuator for depressing the suction generating means.

Therefore, it can be seen that each of the prior art references cited in the Official Action do not teach the present invention of utilizing a gimbaled actuator to provide constant pressure to a compressible member. More particularly, the prior-art references cited do not provide any suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Thus, applicant believes that the Examiner is impermissibly using the applicant's invention as a blueprint for the combination sought because the references do not teach or suggest a **gimbaled actuator** for compressing a bladder. Therefore, because the prior art referenced cited do not teach or suggest the present invention, applicant respectfully requests that the 35 U.S.C. §103(a) rejection be withdrawn and the application advanced to allowance.

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Conclusion

In view of the above remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue.

If the Examiner finds that a Telephone Conference would expedite prosecution of this application, he is invited to contact the undersigned (650) 327-3400.

In the event that the transmittal letter is separated from this document and the Patent Office determines that extensions or other relief is required and/or fees are due applicants, the Applicant petitions for any required relief, including extensions of time, and authorize the Commissioner to charge our Deposit Account No. 50-0815, Order Number LIFE-010, for any fees due in connection with the filing of this document. The Patent Office is not authorized to charge issue fees to our Deposit Account.

Respectfully submitted, BOZICEVIC, FIELD & FRANCIS LLP

Date: 6/4/2000

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